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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,804

09/12/2003

Gerold Schuler

1430/16

8361

25297

7590

05/05/2006

JENKINS, WILSON, TAYLOR &amp; HUNT, P. A.

3100 TOWER BLVD

SUITE 1200

DURHAM, NC 27707

EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/661,804	<b>Applicant(s)</b> SCHULER ET AL.	
	<b>Examiner</b> Celine X. Qian Ph.D.	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12 and 24-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1003</u> . | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

Claims 12, 24-27 are pending in the application.

***Election/Restrictions***

Applicant's election without traverse of Group IV in the reply filed on 3/16/06 is acknowledged.

Accordingly, claims 12, 24-27 are currently under examination.

***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 3/12/2001. It is noted, however, that applicant has not filed a certified copy of the 01106033.2 application as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12, 24-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Jonuleit et al (see IDS).

The claims are drawn to a method of identify, monitor and/or remove CD4+CD25+ cells from human blood by contacting the blood with ligands specifically bind to CD4 and/or CD25 and/or CTL-A4 entities on the T cells. Claim 24 is further drawn to said method, wherein the

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ligands are antibodies. Claim 25 is further drawn to said method wherein CD4+CD25+ cells are removed from the sample. Claim 26 is further drawn to said method wherein immunoadsorption method is used. Claim 27 is drawn to said method wherein the cells are stimulated with stimulating agents or APC.

Jonuleit et al. disclose a method that of identify, monitor and/or remove CD4+CD25+ cells from human blood by contacting the blood with CD4 and/or CD25 and/or CTL-A4 specific antibodies (see page 1214, 2<sup>nd</sup> col., 4<sup>th</sup> paragraph, lines 1-6, and Figure 4). Jonuleit et al. further disclose that CD4+ T cells are removed from the cord blood (page 1214, 2<sup>nd</sup> col., 4<sup>th</sup> paragraph, lines 1-3). Jonuleit et al. also disclose that the purification is carried out using antibodies attached to beads (page 1214, 2<sup>nd</sup> col., 4<sup>th</sup> paragraph, last two lines). Lastly, Jonuleit et al. disclose said method wherein the cells are stimulated with dendritic cells (see page 1215, 1<sup>st</sup> paragraph, lines 2-4). Therefore, Jonuleit et al. disclose the instantly claimed invention.

Claims 12, 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Horwitz (US 6,803,036).

Horwitz et al. disclose a method that of identify, monitor and/or remove CD4+CD25+ cells from human blood by contacting the blood with CD4 and/or CD25 and/or CTL-A4 specific antibodies (see for example Figure 9 and 10A, and col. 7, lines 49-65, and col. 21, lines 60-67). Horwitz et al. further disclose that CD4+ T cells are removed from the cord blood (col. 7, lines 8-12). Horwitz et al. also disclose that the purification can be carried out using antibodies attached to solid support (col. 11, lines 60-65). Lastly, Horwitz et al. disclose said method wherein the cells are stimulated (see col.23, lines 6-12). Therefore, Horwitz et al. disclose the instantly claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 12, the recitation of “ ligands specifically binding to CD4, and/or CD 25, and/or CTL-A4 entities on T cell” renders the claim indefinite because it is unclear how a CD4+CD25+ population of cells can be identified using only one of the specific ligand. It appears that the claimed method is missing essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Therefore, the claim is indefinite. Claims 24-27 are rejected because they depend on claim 12.

Claim 24 recites the limitation "TL-4A" in line 2. There is insufficient antecedent basis for this limitation in the claim. The parent claim (12) recites CTL-A4. It is unclear whether TL-4A is the same or different molecule.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

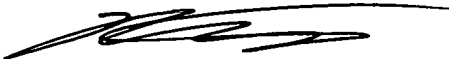
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Celine X Qian', with a long horizontal stroke extending to the right.